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Safety and efficacy of 30% hydrogen peroxide in seborrheic keratoses – A prospective and interventional study

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ABSTRACT

Background: Seborrheic keratosis (SK) is a skin condition affecting the keratinocytes. Although various treatment options are available, the need for a simpler topical treatment approach is unmet. Hydrogen peroxide (HP) acts by forming free radicals and initiates apoptosis in cells. **Aims and Objectives:** The aim of this study was to evaluate the safety and efficacy of 30% HP in SK. **Materials and Methods:** This study was conducted on patients attending the Dermatology, Venereology, and Leprology at MGM Hospital attached to Kakatiya Medical College, Warangal and Government Medical College Mahabubabad, Telangana, during the period from December 2019 to May 2021. In total, 80 adult patients with SKs were enrolled. The study was approved by the Research Ethics Committee of the MGM Hospital attached to Kakatiya Medical College. This is a prospective and interventional study. Eighty patients will be treated with 30% of HP topically. A photographic record of the pre- and post-treatment appearance of lesions was maintained. Physician's lesion assessment (PLA) score was evaluated on day 15th and 106th day after treatment. Local skin reactions (LSRs) were divided into mild, moderate, and severe categories. LSR was observed immediately after 2 weeks and 106 days of treatment. **Results:** Most of the patients were of middle to elderly age group. SK lesions were most common seen over the head and trunk. The dermatosis papulosa nigra variant was the most common. PLA 0 was observed by day 15 in some patients after application. Of 30% HP, faster healing rates were observed in lesions over the face, and middle aged. **Conclusion:** About 30% HP is a promising option for the treatment of SK.

Key words: Seborrheic keratosis; Skin; Epidermis; Keratinocytes; Hydrogen peroxide

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INTRODUCTION

Seborrheic keratoses (SKs) are among the most common benign skin lesions, affecting the Indian population.[1] They commonly appear on the face, chest, shoulders, or back and present as light tan, brown, or black papules or plaques with a waxy, "stuck on," appearance. The etiopathology of SKs is not completely known. They are thought to be a marker of aging skin caused by continuous ultraviolet exposure.[2] SK lesions are well-defined, round, or oval-shaped, usually raised and stuck on the skin. Comedo-like openings and milia-like cysts characterize the dermoscopic appearance of SKs.[3,4] Other features are fissures and ridges, fingerprint-like structures, hairpin vessels, moth-eaten borders, and network-like structures.[5] Diagnosis of SKs is primarily a clinical one and dermoscopy is a non-invasive method for diagnosis.[1,6]

Common techniques for SK removal involve cryosurgery, electrosurgery, curettage, or surgical excision. There is,

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however, a notable lack of well-controlled clinical studies evaluating the efficacy and complication rates of these procedures. Thus, there is a significant and unmet need for a safe, effective, non-invasive, and cosmetically acceptable treatment for this common condition, and pharmacological therapy includes tazarotene (0.1%) cream, imiquimod (5%) cream, benzoyl peroxide, and Vitamin D analogs.[7,8]

Hydrogen peroxide (HP) is a member of the reactive oxygen species (ROS). It has a variety of functions in biology and medicine. In its pure form, it is light blue. In the diluted form, it is a colorless, odorless, and water-soluble liquid. It consists of hydrogen and oxygen.[9] There are many different natural sources of HP. It is thought to be an inevitable by-product of oxygen metabolism.[3,9] The mechanism of action is by oxidative damage of lipids, proteins, and nucleic acids, either directly or indirectly through the production of hydroxyl radicals (*OH) and downstream propagation of additional ROS.[10] HP solution is the first and only US Food and Drug Administration-approved topical treatment for raised SKs.

Aims and objectives

This study aimed to evaluate the safety and efficacy of 30% of HP in SKs.

MATERIALS AND METHODS

This study was conducted on patients attending the Dermatology, Venereology, and Leprology at MGM Hospital attached to Kakatiya Medical College, Warangal and Government Medical College Mahabubabad, Telangana, during the period from December 2019 to May 2021. In total, 80 adult patients with SKs were enrolled. The study was approved by the Research Ethics Committee of the MGM Hospital attached to Kakatiya Medical College.

All participants underwent full history taking and complete general and dermatological examinations to detect the site, size, and number of SK lesions and collected the demographics data such as patient's age, sex, occupation, thorough clinical history regarding onset, duration, site of the lesion, number of lesions, sun exposure, family history, and treatment taken previously for the condition were noted.

Study design

This was to prospective and interventional study.

Experimental study

All the patients were informed regarding the nature of the disease, treatment options, and prognosis. These patients will be treated with 30% of HP topically. After a clinical diagnosis of the lesions, topical HP will be applied sequentially to the lesions for 20 s/SKs at each pass, for a total of four passes, 1 min apart. Efficacy will be measured at the end of the 2nd and 15th weeks using the validated physician's lesion assessment (PLA) scale, in which 0=clear (no visible SK); 1=near-clear (visible SK, not raised); 2=thin SK (≤1 mm); and 3=thick SK (1 mm). If any SK is not clear 2 weeks (15th day) after the first treatment, a second treatment will be administered. Response was evaluated by complete disappearance or decrease in size or number of lesions and documentation of any adverse side effects by the end of 15 weeks (106th day) was done. A photographic record of the pre- and post-treatment appearance of lesions was maintained. Local skin reactions (LSRs) were divided into mild, moderate, and severe categories. LSR was observed immediately after 2 weeks and 106 days of treatment.

Inclusion criteria

Patients aged more than 18 years were included in this study. Patients with single or multiple SKs have a clinically typical appearance and with a PLA scale of ≥2. Patients with good general health and free of any known disease state or physical conditions that might impair evaluation of any target lesion or which expose the subject to an unacceptable risk by study participation.

Exclusion criteria

An exclusion criterion was patients with multiple eruptive SK lesions. Patients with SKs in intertriginous folds, pregnant, and lactating women. Patients used any topical therapies at or in proximity to any target lesion. Patients had a history of sensitivity to any of the ingredients in the study medications. Lesion assessment was done at the specified periods during the study using a PLA scale.

Statistical analysis

Data were collected, revised, coded, and entered into the Statistical Package for the Social Science (IBM SPSS) (Armonk, New York, USA), version 23. The quantitative data with parametric distribution were presented as mean, standard deviations, and ranges, while the parametric distribution was presented as median with interquartile range. Furthermore, qualitative variables were presented as numbers and percentages. The comparison between groups regarding qualitative data was done using the χ^2 test and/or Fisher's exact test when the expected count in any cells was found <5. The comparison between two independent groups with quantitative data and parametric distribution was done using an independent *t*-test, while nonparametric distribution was done using the Mann–Whitney test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. Hence, the P-value was considered significant as the following: P>0.05: Non-significant. P<0.05: Significant. P<0.01: Highly significant.

RESULTS

Eighty patients were included in the SKs study. Most patients in this study belonged to the age group <30 years (45%). Among 80 patients, 37 were males and 43 were females, with a ratio of 1:1.16. The onset of SKs was most common in the age group 21–30 (35 cases). Predominant SK cases were shown by farmers (35%) and exposed to sunlight. Fitzpatrick skin photo Type IV (45 cases) or V (35 cases) Table 1 shows patient demographics.

The highest number of cases had SK on the head and neck (73 cases, i.e., 91.25%). A positive family history was present in 15 cases, that is, 18.75% out of 80 cases. A total of 695 lesions were recorded; of these, 539 (77.55%) were on the exposed area and 156 (22.45%) were on the non-exposed area. The average number of lesions on the exposed area per person was 6.7, and on the non-exposed area, it was two per person.

The most common clinical variant was dermatosis papulosa nigra (41 cases i.e. 51.25%) followed by other clinical variants like CSK (23 cases i.e. 28.75%), flat SK (11 cases i.e. 13.75%), stucco keratosis (6 cases i.e. 7.5%), and pedunculated SK (4 cases i.e.5%). Out of 80 cases, 46 cases had only one clinical variant and 34 cases had two or more than two clinical variants in them.

LSRs were divided into mild, moderate, and severe categories. LSR was observed immediately after 2 weeks and 106 days of treatment. Table 2 shows the percentage of lesions with LSRs. Immediately after treatment; we found results of edema in 46, 15, and 4 cases (57.5%, 8.75%, and 4%, respectively). In the 2nd week (15th day), we observed hyperpigmentation (Hyp) and hypopigmentation (Hypo), with Hypo varying in severity from mild-to-moderate in 43 and 13 cases, respectively. In this study, 12 cases out of 56 retained Hypo, and three cases out of six retained Hyp.

The PLA is a measure of the visibility or thickness of an SK measured on a scale from 0 to 3. In this study, PLA scores 2 and 3 were found in 28 (35%) cases and 52 (65%) cases, respectively. Table 3 shows the PLA score in treatment on the 15th and 106th days. In this study, the number of patients that achieved a PLA score of 0 in 4/4 lesions at day 15 was 10, and in 3/4 lesions was 18. A statistically significant number of patients showed improvement with one session of treatment with 30% of HP at the end of 2 weeks. In this study, 22 cases out of 80, that is, 27.5%, showed improvement in PLA with a score of 0 in 3/4 lesions at day 106 when the patient was reassessed. 32 cases out of 80, that is, 40%, showed a PLA of 0 in 4/4 lesions at 106 days. Twenty-six cases out of 80, that is, 26%, had a PLA score of ≥1. The P=0.00738. The result is significant at P<0.05. The above statistically significant results at 15 and 106 days show that treatment with 30% of HP can achieve complete clearance of lesions by the 106th day.

Table 1: Patient demographics

Characteristic	Male, n (%)	Female, n (%)	Total (n=80), n (%)
Sex	37 (46.25)	43 (53.7)	
Age and sex distribution			
<30	16 (20)	20 (25)	36 (45)
31–40	8 (10)	12 (15)	20 (25)
41–50	8 (10)	10 (12.5)	18 (22.5)
51–60	3 (3.75)	1 (1.25)	4 (5)
61–70	1 (1.25)	0	1 (1.25)
>70	1 (1.25)	0	1 (1.25)
Age on set			
11–20		1 (1.25)	
21–30		35 (43.75)	
31–40		23 (28.75)	
41–50		17 (21.25)	
51–60		4 (5)	
61–70		0	
>71		0	
Occupation			
Professionals		8 (10.00)	
Farmers		28 (35.00)	
Housewives		15 (18.75)	
Businessmen		14 (17.50)	
Manual laborers		7 (8.75)	
Students		6 (7.50)	
Others		2 (2.50)	
Fitzpatrick skin type			
I		0	
II		0	
III		0	
IV		45 (56.25)	
V		35 (49.75)	
VI		0	
Clinical variants			
DPN		41 (51.25)	
CSK		23 (28.75)	
FSK		11 (13.75)	
STK		6 (7.50)	
PSK		4 (5)	

DPN: Dermatosis papulosa nigra, CKS: Common seborrheic keratosis, FSK: Flat seborrheic keratosis, STK: Stucco keratosis, PSK: Pedunculated seborrheic keratosis

The treatment-emergent adverse events show that four out of 80 cases had a burning sensation at the treatment site, and five cases complained of pain at the site. Figure 1 shows SK patient photographs before and after HP30 treatment.

DISCUSSION

The hydroxyl radicals overcome the cell's antioxidant defenses, ultimately producing cell damage and inducing apoptosis. Supraphysiological concentration of HP causes the death of keratinocytes; ultimately, leading to the resolution of the lesions. HP30 is administered by a healthcare provider. It comes as a one-time applicator pen that is prefilled with the drug. When the pen is squeezed, the drug is activated and fills the tip of the pen. The pen

Table 2: Percentage of lesions with local skin reactions

LSR	Immediately after treatment				At the end of 2 weeks				LRS at 106-day			
	Mild, n (%)	Moderate, n (%)	Severe, n (%)	Total, n (%)	Mild, n (%)	Moderate, n (%)	Severe, n (%)	Total, n (%)	Mild, n (%)	Moderate, n (%)	Severe, n (%)	Total, n (%)
Edema	46 (57.5)	15 (18.75)	4 (5)	65 (81.25)	-	-	-	-	-	-	-	-
Erythema	12 (15)	6 (7.5)	2 (2.5)	20 (25)	6 (7.5)	-	-	6 (7.5)	-	-	-	-
Crusting	3 (3.75)	1 (1.25)	-	4 (5)	1 (1.25)	-	-	1 (1.25)	-	-	-	-
Stinging	25 (31.25)	8 (10)	2 (2.5)	35 (43.75)	-	-	-	-	-	-	-	-
Pruritus	2 (2.5)	-	-	2 (2.5)	1 (1.25)	1 (1.25)	-	2 (2.5)	-	-	-	-
Scaling	-	-	-	-	7 (8.75)	-	-	7 (8.75)			12	12
Hyperpigmentation	-	-	-	-	6 (7.5)	-	-	6 (7.5)	-	-	3	3
Hypopigmentation	-	-	-	-	43 (53.75)	13 (16.25)	-	56 (70)	-	-	-	-
Scarring	-	-	-	-	2 (2.5)	-	-	2 (2.5)	-	-	-	-

LSR: Local skin reaction

Table 3: Physician lesion assessment score of lesions

Score	PLA score on 15th day, n (%)	PLA score on 106th day, n (%)
PLA score of 0 in 3/4 lesions	10 (12.50)	22 (27.50)
PLA score of 0 in 4/4 lesions	18 (22.50)	32 (40.00)
PLA score≥1	52 (65)	26 (33)

PLA: Physician lesion assessment

tip is then applied directly to the SK; it should be applied in a circular motion for about 20 s or until the lesion is wet with the medication.[11] Patients frequently present to dermatologists seeking treatment for cosmetic or physical (e.g., itching) or psychosocial reasons, as well as for concerns about malignancy. The prevalence of SKs increases with age, ranging from 38% in people aged 24–49 years to >90% in those 70 years and older.

SKs are very common benign epithelial skin tumors in the adult population. Common techniques for SK removal include cryosurgery, electrosurgery, curettage, and surgical excision.[6] HP may act through its direct oxidation of organic tissues, generation of ROSs, local lipid peroxidation, and generation of oxygen, that is, toxic to SK cells.[11] The safety and efficacy of 30% of HP in SKs are being evaluated, along with its side effects. To the best of our knowledge, there were no previous studies that evaluated the efficacy of topical 30% of HP solutions.

SK occurs as early as in adolescence and is common in middle-aged and elderly individuals. Males and females are equally affected. Our study had a male-to-female ratio being 1:1.16 (37 males and 43 females). Yeatman et al.,[12] found that there was no significant difference between men and women with a male-to-female ratio of 1:1.08 (48 males and 52 females) SK can appear at any age but their incidence increases with age. In the present study, the most commonly affected age group was 51–60 years followed by 61–70 years. Similar to the present study, Yeatman et al.,[12] observed that 100% of patients in age groups 51–75 years and above 71 years of age were affected, proving that SK is more common in middle and elderly age groups.

Distribution of SK can occur on any part of the body it usually affects the face and upper trunk. In our study out of 695 lesions recorded, the majority (n=539 [77.5%]) of the lesions were in sun-exposed areas and 156 (22.5%) were in non-exposed areas. The average number of lesions on the exposed area was 6.7 per person and on non-exposed was 2 per person. Most of the lesions were on the head and neck (73 cases i.e. 91.25%) followed by the chest (8 cases i.e. 10%). In a Korean study by Kwon et al.,[13] SK was considerably more frequent in exposed areas than partly exposed areas. The majority of lesions were concentrated on the face and the

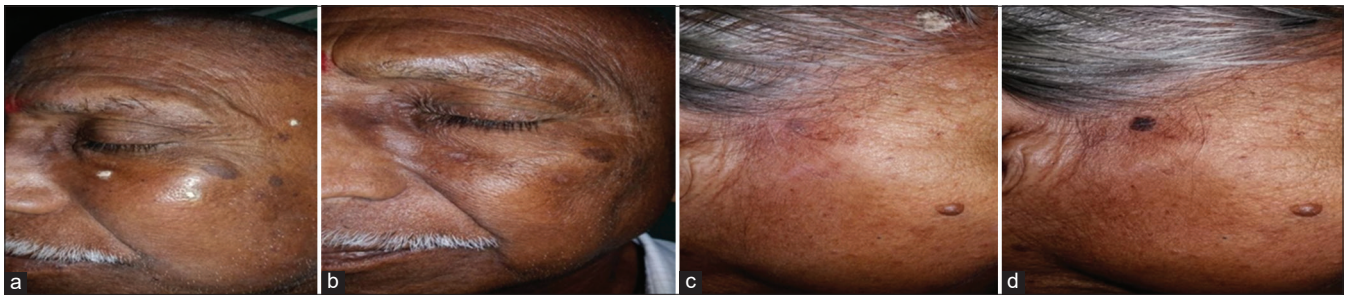

Figure 1: Seborrheic keratosis patient photographs of before and after hydrogen peroxide 30 treatment: (a) male before treatment (b) male after treatment, (c) female before treatment (d) female after treatment

dorsum of each hand. The authors in this study indicated that excessive sun exposure is an independent risk factor for SK.

Morphology of SKs begins usually as dull, flat, well-circumscribed tan brown macules which later grow to become papular, waxy with a stuck-on appearance, or verrucous. Papular lesions were most common (56 cases i.e. 70%) followed by plaque type (45 cases i.e. 56.25%). Similar findings were observed in studies done by Kwon et al.,[13] Rajesh et al.,[14] and Braun et al.[15]

The efficacy of 30% of HP in the treatment of SK, in this study, PLA score assessments were performed on the 10th day, 15th day, and 106th day. Out of 80 cases, 52 cases, that is, 65% had a PLA score of 3, and 28 cases had a score of 2 at baseline assessment (day-10). On day 15 after the first session, patients were reassessed for PLA score, and, in 20 out of 80 cases, that is, 25% achieved a PLA score of 0 in three out of four lesions and in 12 cases, that is, 15% achieved a 0 PLA score in four out of four lesions. Fifty-two cases out of 80 (i.e. 65%) showed a score of ≥1. A reassessment of the PLA score was performed on day 106, during post-treatment follow-up after two sessions of treatment with 30% HP. PLA score of 0 in three out of four lesions was achieved in 22 cases, that is, 27.5% and 4/4 lesions showed clearance in 32 cases, that is, 40%.26 cases, that is, 32.5% had a PLA score ≥1 on the 106th day. The results of our study showed a good efficacy of 30% of HP with a statistically significant P-value. A comparative study between 40% of HP and vehicle was performed by Baumann et al.,[12] in 2018. In this trial, 450 and 487 patients were enrolled in study 1 (223 in the HP group and 227 in the vehicle group) and study 2 (244 in the H_2O_2 group and 243 in the vehicle group), respectively. Statistically significantly more patients in the HP group achieved complete clearance than in the vehicle group. Salecha et al.,[4] reported that in a study between 40% of HP and 50% of TCA, a total of 40 patients with 20 in each group were studied. Patients were given treatment every 2 weeks for a maximum of three sessions and followed up for 1 month after the last session. After completion of all sessions, patients treated with HP achieved a PLA scale of 0 (total clearance) at 45%, whereas in TCA, it was 25%, with a significant P-value (<0.0001).

The safety of 30% of HP was evaluated by LSR parameter, it was observed that erythema (91% of lesions) was the most common LSR, followed by edema (75%). About 45% of lesions had mild stinging sensation. Pruritus was reported in 12% and vesicle formation was reported in 10% of lesions. Scaling and crusting were observed 1 week after the initial treatment (in 49% and 45% of lesions, respectively). In our study, we found that there were few persisting as well as new LSRs at the end of 2 weeks (day 15) post-treatment. The most common LSR on day 15 was mild Hypo (70%). Other LSRs observed on 15th day after treatments were Scarring (2.5%), scaling (8.75%), erythema (7.5%), Hyp (7.5%), crusting (1.25%), and pruritus (1.25%). In contrast to our study, Baumann et al.,[12] observed scaling (49%) and crusting (45%) as the most common LSRs 1 week after treatment initiation. This difference could be attributed to the difference in Fitzpatrick skin phototype as all the cases in our study belonged to phototypes IV and V. Only 12 cases had residual Hypo and three cases had residual Hyp. All other LSRs were not observed on the 106th day. This remnant Hypo and Hyp also disappeared at the end of 6 months. This shows that all the LSR in our study were mild, transient, and disappeared at the end of the study. The results in our study were consistent with Dubois et al.,[16] studies, this shows similarities in efficacy and safety between 30% of HP and 40% of HP.

In our study, faster resolution of lesions was observed in the age group <40 years. Seven patients out of 24 (29.2%) in the age group >40 years showed improvement after a single session and 21 out of 56 (37.5%) in <40 age group had improvement with one session. No age-related adverse effects to treatment were observed in our study. These findings were by the preliminary study performed by Keaney[17] and Funkhouser et al.[18]

Limitations of this study

The number of sessions in this study was limited to two by protocol, to assess the efficacy of 30% HP. The patients in this study had Fitzpatrick skin phototypes of IV or V. Due to the relative homogeneity of the study population, the results in this study cannot be attributed to all phototypes.

CONCLUSION

SK is a common benign epidermal tumor for which treatment is not necessary but may be pursued by the patients for cosmetic and symptomatic improvement. The most common treatment for SK currently is cryotherapy; however, it can be painful and cause scarring and skin pigmentation alterations. This study concludes that 30% of HP could be a potential, novel, cost-effective, non-invasive treatment for SKs. Faster healing was observed in lesions on the head and neck, lesions on non-exposed sites, lesions with lower PLA scores on the day of assessment, and in patients < 40 yrs.30% HP solutions were effective in the treatment of SKs with no significant side effects.

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Authors Contribution:
TUR – Concept and design of the study prepared the first draft of the manuscript; **AS and MM –** Interpreted the results, reviewed the literature, and manuscript preparation; **SN, BV,** and **MKRT** – Concept, coordination, statistical a,nalysis, and interpretation, preparation of manuscript and revision of the manuscript.

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